

U.S. ENVIRONMENTAL PROTECTION AGENCY ADMINISTRATOR ANDREW WHEELER

MEMORANDUM FOR AWARENESS

Date of Submission: Friday, September 25, 2020

TOPICS FOR DISCUSSION

1. ISSUE/REQUEST: OCSPP Plans to Publish Seven Federal Register Notices with the Following Pesticide Registration Review Activities

- As OSCPP proceeds through the four-step registration review process for over 725 pesticide active ingredients, during the week of October 12, the agency will notice the availability of the documents below for public comment.
- For the most part, no proactive communications are planned for these procedural announcements; OCSPP will have subject matter experts assist with press inquiries should they come in.

I. Notices of Availability – Preliminary Work Plan

The preliminary work plan is the first step in the four-step registration review process. Depending on the volume of comments expected and the nature of the pesticide, OCSPP notices availability of the documents in groups.

A. Preliminary Work Plan for Three Pesticides:

This notice announces the availability of preliminary work plans for the registration review of Aminocyclopyrachlor (ACP), Cetylpyridinium Chloride (CPC), and Flutriafol.¹

i. Aminocyclopyrachlor (ACP):

Preliminary Work Plan Summary: The most recent human health and ecological risk assessments were conducted in 2020. The recent human health risk assessment found no risks of concern. The ecological risk assessment found risks of concern to non-target terrestrial plants. ACP is in the pyridine and pyrimidine carboxylic acid group of herbicides, which are very persistent and are known to cause non-target plant damage from compost contamination. Residues in treated plant matter can contaminate compost through turf clippings or manure from animals that have grazed on treated plants. ACP is even more persistent than other persistent pyridine/pyrimidine carboxylic acid herbicides.

Anticipated Stakeholder Reaction: ACP is the most persistent of all the pyridine/pyrimidine herbicides. A large volume of comments is expected from the public

Briefing Paper Author Contact: Alex Dunn (202) 819-5156

¹ XXXXX-XX, Notice, Pesticide Registration Review; Preliminary Work Plans for Several Pesticides; Notice of Availability

on the potential for compost contamination. The U.S. Composting Council has organized a mass mail campaign for clopyralid, another compost herbicide, previously, and is expected to be very vocal in advocating for more restrictive measures from EPA.

ii. Cetylpyridinium Chloride (CPC):

Preliminary Work Plan Summary: The most recent human health risk assessment from 2008 identified a battery of toxicity studies as data gaps. The agency expects to require these additional data to conduct a human health risk assessment for registration review. The agency has not previously conducted a risk assessment that supports a complete endangered species determination for CPC. The anticipated ecological risk assessment planned during registration review will allow the agency to determine potential acute and chronic risks to aquatic organisms exposed to CPC that is transported from the treatment sites and its aerobic soil metabolism degradate pyridinium hexyl carboxylic acid (PHC) that can run off from soil adjacent to treated materials containing CPC.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

iii. Flutriafol:

<u>Preliminary Work Plan Summary:</u> The most recent human health risk assessment was completed in 2019 and found no risks of concern. A quantitative spray drift assessment is anticipated as part of registration review. The most recent ecological risk assessment was completed in 2011 and found some slight level of concern (LOC) exceedances for birds and mammals foraging in short grass and for non-target aquatic vascular plants. It is anticipated that the full suite of Tier I pollinator data will be called in as part of registration review.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

II. Notices of Availability – Draft Human Health/Ecological Risk Assessments The draft human health and ecological risk assessments are the second step in the four-step registration review process. Depending on the volume of comments expected and the nature of the pesticide, OCSPP notices availability of the documents in groups.

A. Draft Human Health and Ecological Risk Assessments for Zinc Phosphide OCSPP will announce the availability of draft human health and ecological risk assessments for zinc phosphide.²

² XXXXX-XX, Notice, Pesticide Registration Review; Draft Human Health and/or Ecological Risk Assessments for Zinc Phosphide; Notice of Availability

- <u>Ecological Risks:</u> The draft risk assessment provided multiple lines of evidence indicating risk of mortality to terrestrial vertebrates through direct consumption of bait and secondary poisoning via consumption of contaminated prey. There are many incident reports involving wildlife and pets. Risks are considered to be low for aquatic animals, aquatic and terrestrial plants and terrestrial invertebrates.
- <u>Human Health Risks:</u> A qualitative dietary assessment approach was conducted based on low presence of residues and to be consistent with the phosphine dietary assessment. Occupational exposure is anticipated; however, a qualitative assessment was conducted. This strategy aligns with the agency's risk management goals for all of the rodenticides to minimize non-target (human) exposure. Dermal toxicity data are outstanding but are not required for registration review given that the risk assessment is qualitative.

<u>Anticipated Stakeholder Reaction:</u> No communications are expected beyond posting in the Federal Register and receiving comments during the public comment period, but a high volume of comments are expected.

B. Draft Human Health and/or Ecological Risk Assessments for 17 Pesticides:

This notice announces the availability of draft human health and/or ecological risk assessments for the registration review of 4-Aminopyridine (4-AP), Benzoic Acid, Benzyl benzoate (benylate), Butoxypolypropylene glycol (BPG), Cycloate, Difenoconazole, Dimethoxane, Fenbuconazole, Ferbam, HPPD Inhibitors (Isoxaflutole, Mesotrione, Tembotrione, Topramezone, and Pyrasulfotole), Organic Esters of Phosphoric Acid (OEPA), Phorate, Phosmet, Polymeric Betaine, Thiram, Tolfenpyrad, and Ziram.³

iv. 4-Aminopyridine (4-AP):

<u>Summary of Ecological Risks</u>: There are potential risk concerns for birds and mammals on an acute basis (chronic risk uncertain). There is a low potential for risk for fish, aquatic invertebrates, and aquatic and terrestrial plants. Risk to terrestrial invertebrates is not expected due to limited exposure pathways from limited application methods (bait by tray).

<u>Summary of Human Health Risks:</u> No dietary exposure from food or water is expected based on the use patterns. Residential applicator exposure is not expected since 4-

³ XXXXX-XX, Notice, Pesticide Registration Review; Draft Human Health and/or Ecological Risk Assessments for Several Pesticides; Notice of Availability

aminopyridine can only be applied by certified applicators. There is no concern for occupational applicators.

<u>Anticipated Stakeholder Reaction:</u> No additional communications are planned. This chemical has attracted attention over the potential risk to non-target species, particularly those protected by the Migratory Bird Treaty Act.

v. Benzoic Acid:

<u>Summary of Ecological Risks:</u> The risk to terrestrial and aquatic organisms (including plants) is expected to be negligible. At this time, the agency concluded that based on low hazard and exposure, the registered uses of benzoic acid will have a "no effects" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species.

Summary of Human Health Risks: Human dietary exposure to residues of benzoic acid from pesticidal sources is expected to be minimal compared to the direct food-additive uses regulated by FDA. Therefore, a qualitative dietary assessment has been performed. For the currently registered uses of benzoic acid, short- and intermediate-term dermal and inhalation exposures are likely during open-pour loading and mixing to occupational handlers. With appropriate personal protective equipment (PPE), exposures are expected to be minimal and with the relatively low toxicity of benzoic acid, no adverse effects are expected from exposure to the currently registered antimicrobial products.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

vi. Benzyl benzoate (benylate):

<u>Summary of Ecological Risks</u>: The ecological risk assessment for benzyl benzoate was posted in the docket in 2016, with a "no effects" determination for listed species.

<u>Summary of Human Health Risks:</u> No dietary exposures are expected. No inhalation risks of concern were identified.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

vii. Butoxypolypropylene glycol (BPG):

Summary of Ecological Risks: No potential ecological risks of concern are anticipated.

Summary of Human Health Risks: There are no risks of concern.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

viii. Cycloate:

<u>Summary of Ecological Risks:</u> The ecological draft risk assessment identified risks to mammals, terrestrial invertebrates, aquatic plants, and potentially terrestrial plants based on registered uses. For all uses, potential risk was similar for all application types. Mortality in the chronic adult honeybee toxicity study results in the potential for risk to bees on treated fields for garden and sugar beet crops grown for seed. No colony-level effects data are available for honeybees, but OSCPP will work to call-in additional colony-level data.

Summary of Human Health Risks: In 2014, a 10x uncertainty factor was added to both acute and chronic dietary exposures for lack of a developmental neurotoxicity study (DNT). A request to waive that study was recently denied. The agency also applied a 10x to dermal occupational scenarios. There are no acute dietary risks of concern. However, chronic dietary exposures were above the level of concern. The major contributor is drinking water. There are risks of concern for occupational handler scenarios, as well as occupational applicator scenarios. Risks for some, but not all, scenarios are mitigated with PPE. There are no residential exposures, so aggregate risks are equivalent to the dietary (food + drinking water) analyses. Non-occupational spray drift was not conducted.

<u>Anticipated Stakeholder Reaction:</u> In addition to posting in the Federal Register for public comment, the agency plans to develop a desk statement due to the DNT requirements.

ix. Difenoconazole:

<u>Summary of Ecological Risks</u>: For the ecological risk assessment, there are potential chronic risks of concern to birds, mammals, fish, invertebrates, and aquatic plants and acute risks of concern for saltwater invertebrates. Difenoconazole has the potential to bioaccumulate in the aquatic food web and be of an exposure concern to piscivorous birds and mammals. There were no acute or chronic LOC exceedances in the aquatic food-web based model (KABAM).

Summary of Human Health Risks: No of concern.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

x. Dimethoxane:

<u>Summary of Ecological Risks:</u> Dimethoxane and its degradates are not expected to result in risk to terrestrial or aquatic species (including pollinators). Based on the low exposure potential from antimicrobial uses of dimethoxane as well as low toxicity to non-target terrestrial and aquatic organisms, the agency has made a "no effects" determination for dimethoxane under the ESA for all listed species and designated critical habitats for such species.

<u>Summary of Human Health Risks:</u> There are no residential handler risks of concern, nor are there are occupational dermal or inhalation risk of concerns for dimethoxane.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xi. Fenbuconazole:

<u>Summary of Ecological Risks</u>: Risks were identified to the following taxa: chronic risk to mammals, acute risks to larval bees, acute and chronic risk to freshwater and estuarine/marine fish, chronic risk to freshwater (water-column) invertebrates, risk to estuarine/marine sediment-dwelling invertebrates, and potential risks to mammalian species via consumption of aquatic organisms.

Summary of Human Health Risks: No risk estimates of concern.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xii. Ferbam:

<u>Summary of Ecological Risks</u>: The ecological risk assessment shows potential risks to: birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk). Ferbam rapidly (within minutes to hours) breaks down to thiram. As a result, a total toxic residues (TTR) approach was used which conservatively considered exposure and toxicity considerations of both compounds.

Summary of Human Health Risks: The human health risk assessment resulted in no acute or chronic dietary (food and drinking water) risks of concern. Acute and chronic aggregate risk estimates include food and drinking water only and are not of concern. Most occupational handler scenarios result in dermal and/or inhalation risk estimates of concern even with additional PPE or engineering controls. Most occupational post-application scenarios result in dermal risk estimates of concern at the current label Restricted Entry Interval (REI) of 24 hours (one day after treatment). Some scenarios are still of concern at 30 days, or longer, after treatment. Indirect exposures to ferbam as a result of spray drift are not of concern.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xiii. HPPD Inhibitors (Isoxaflutole, Mesotrione, Tembotrione, Topramezone, and Pyrasulfotole):

<u>Summary of Ecological Risks</u>: Ecological risks vary across the HPPD Inhibitors, however potential risks are primarily for non-target terrestrial/aquatic plants. In addition, potential risks of concern were identified to mammals for pyrasulfotole, tembotrione, and topramezone and risks to birds for topramezone. Some of the Tier 1 honeybee studies have not yet been submitted for isoxaflutole and these will be reviewed/incorporated into any risk assessment revisions in the future.

<u>Summary of Human Health Risks:</u> No human health risks of concern are expected. A screening-level cumulative human health risk assessment is scheduled for completion in Q2 FY21 for the group.

<u>Anticipated Stakeholder Reaction:</u> No communications are planned beyond posting in the Federal Register and the public comment period. No significant opposition from stakeholders is anticipated.

xiv. Organic Esters of Phosphoric Acid (OEPA):

<u>Summary of Ecological Risks:</u> The agency anticipates some of the registered uses of OEPA may result in environmental exposures; and, an endangered species effect determination has not been made.

<u>Summary of Human Health Risks:</u> Based on the use patterns of OEPA, dietary exposure is expected for materials preservation in molded polymer products (e.g., toys). Since the uses of OEPA occur in an indoor environment, it is not expected that OEPA will impact any source of drinking water. There are dermal and inhalation risks of concern for residential and occupational handlers using OEPA-preserved paint (brush and airless sprayer), which registrants have indicated is an important use. There are also post-application residential risks of concern from OEPA-treated mattresses, textile/clothing and carpet/floor shampoos. There are aggregate risks from post-application exposure to treated materials.

Anticipated Stakeholder Reaction: Overall stakeholder reaction is anticipated to be low. OCSPP is releasing a Proposed Interim Decision (PID) concurrently with this assessment and is proposing to lower the paint use rate below what registrants have indicated as desired, so they may comment on the PID and request OCSPP to redo the risk assessment if they have refinements to offer.

xv. Phorate:

<u>Summary of Ecological Risks:</u> There are potential risk concerns for birds/reptiles/terrestrial phase amphibians, mammals, terrestrial invertebrates, fish/aquatic-phase amphibians, and aquatic invertebrates. There are 18 incidents for birds and mammals, three for aquatic animals; phorate residues are associated with these incidents. Two incidents were reported for plants, although a co-applied herbicide was more likely the cause.

<u>Summary of Human Health Risks:</u> A human health risk assessment will be completed for phorate after the SAP meeting this fall. The human health risk assessment for phorate is scheduled for Q2 2021. Comparative Cholinesterase Assay (CCA) data are in development; submission is expected in March 2021 for phorate.

<u>Anticipated Stakeholder Reaction:</u> Significant stakeholder reaction not anticipated at this time.

xvi. Phosmet:

<u>Summary of Ecological Risks:</u> The ecological risk assessment identified risk to birds, mammals, reptiles, amphibians, terrestrial invertebrates, fish, and aquatic invertebrates. Eleven incidents have been reported. Ten involved bees and one was an accidental misuse resulting in a fish kill.

Summary of Human Health Risks: A human health risk assessment was completed in 2016. It will be updated after the SAP meeting this fall. CCA data are in development; submission is expected sometime after November 2020 for the phosmet oxon. CCA data may result in changes to the 2016 phosmet human health assessment.

Anticipated Stakeholder Reaction: Significant stakeholder reaction is not anticipated.

xvii. Polymeric Betaine:

<u>Summary of Ecological Risks</u>: There are no ecological risks of concern. The agency has made a 'no effects' call for listed species and their designated critical habitats.

<u>Summary of Human Health Risks:</u> Dietary exposure via food is not expected because the labels prohibit use on wood that may come into contact with food or feed. Residential post-application dermal and incidental oral exposures are of concern. Occupational dermal and inhalation exposures for composite wood workers and pressure treatment are not of concern. Occupational inhalation exposure for sapstain control worker are also not of concern. Occupational dermal exposure for sapstain control worker are of concern.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xviii. Thiram:

<u>Summary of Ecological Risks</u>: The ecological risk assessment resulted in potential risks to birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk).

<u>Summary of Human Health Risks:</u> No dietary risks of concern were identified in the human health risk assessment. Potential risks of concern for spray drift, golfing on treated turf, some occupational handler scenarios, and some occupational post-application scenarios were identified.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xix. Tolfenpyrad:

<u>Summary of Ecological Risks</u>: The ecological risk assessment resulted in potential risks for all taxa except for terrestrial and aquatic vascular plants.

Summary of Human Health Risks: No risks of concern were identified.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xx. Ziram:

<u>Summary of Ecological Risks:</u> The ecological risk assessment resulted in potential risks to birds, mammals, bees, fish, aquatic invertebrates, and non-vascular plants (terrestrial plants and aquatic vascular plants not at risk). Because ziram rapidly breaks down to thiram (within days) a TTR approach was used which conservatively considered exposure and toxicity considerations of both compounds. For the antimicrobial uses, risks to fish and aquatic invertebrates were identified for the paint use. There are no other risks of concern for any of the other antimicrobial uses for other aquatic or terrestrial taxa.

<u>Summary of Human Health Risks:</u> For the conventional uses, for dietary risk the acute and chronic assessments were refined and there were no risk estimates of concern. For spray drift, risk estimates are of concern for adults and children at the field edge. For occupational handlers, for dermal exposure there were many scenarios of concern and for inhalation exposure all scenarios were of concern with one exception (aerial application for nurseries) even when assessed assuming PPE and, in some cases, with engineering

controls. For occupational post-application, risk estimates were of concern on day 0, except for hand weeding of tomatoes and blueberries. Risk estimates were of concern on Day 0 and on Day 23 for bird control, hand weeding, orchard maintenance, and propping activities for apple/cherry/pear applications. The use of dislodgeable foliar residue (DFR) data did not substantially improve the risk picture. For the antimicrobial uses, the paint use results in an inhalation risk of concern for residential painters.

<u>Anticipated Stakeholder Reaction:</u> Registrants and end users are likely to provide comments on risk assessment conclusions based on scope and degree of risk, and implications for mitigation.

III. Proposed Interim Decisions

The Proposed Interim Decisions (PIDs) are the third step in the four-step process. In the PID, OCSPP proposes mitigation measures to reduce the human health and ecological risks identified in step one, taking into account public comment. For the most part, no proactive communications are planned for these procedural announcements. OCSPP will have subject matter experts assist with press inquiries should they come in.

A. Proposed Interim Decision for Methomyl/Thiodicarb

OCSPP will announce the availability of the PID for methomyl/thiodicarb.⁴

Summary of PID:

The PID will propose the following mitigation and registrants have agreed to these proposed mitigation measures.

- Buffers from residential areas for methomyl labels.
- Mandatory spray drift management language for methomyl labels.
- In addition, OCSPP is soliciting comment (on recommendation from OGC) on the conclusion that uncertainty in the drinking water assessment justifies using the 99.8th percentile of the dietary distribution as the threshold of regulation for methomyl and thiodicarb.
 - o Pending the outcome of these comments, a 100-foot well set-back may be considered as part of the interim decision for methomyl.

Anticipated Stakeholder Reaction:

• Positive stakeholder feedback is expected from growers, USDA, and registrants.

⁴ XXXXX-XX, Notice, Pesticide Registration Review; Draft Human Health and/or Ecological Risk Assessments for Methomyl/Thiodicarb; Notice of Availability

- Some negative feedback from NGOs may be received regarding the 99.8th percentile of regulation argument.
- OCSPP plans to develop a desk statement.

B. Proposed Interim Decision for Paraquat

OCSPP will announce the availability of the PID for paraquat.⁵

- <u>Summary of PID:</u> OCSPP is proposing the following mitigation measures in the PID, to which the registrants have agreed:
 - Prohibit aerial application for all use sites except for cotton (desiccation use only)
 - o Require 75-ft buffer for cotton desiccation
 - Prohibit pressurized handgun and backpack sprayer application methods on the label
 - o Limit maximum application rate for alfalfa to 1.0 lb a.i./A
 - o Require enclosed cabs if area treated in 24-hr period is more than 80 acres
 - Require enclosed cabs or PF10 respirators if area treated in 24-hr period is 80 acres or less
 - o 48-hr REI for all crops/uses except for cotton desiccation
 - 7-day REI for cotton desiccation
 - o Mandatory spray drift management
 - Label changes to exempt truck drivers from the current requirement to be a certified applicator in order to transport paraquat

Anticipated Stakeholder Reaction: Positive stakeholder feedback is expected from the cotton industry, due to prior communication with cotton growers and extension specialists regarding paraquat's use on cotton. For communications, OCSPP is planning a web update, desk statement, OPP Update and Qs & As.

C. Proposed Interim Decisions for 22 Pesticides

OCSPP will announce the availability of proposed interim registration review decisions and open a 60-day public comment period on the PIDs for the following 22 pesticides: 1,3-Dichloropropene (Telone), 1-Methylcyclopropene, *Beauveria bassiana*, Benzyl benzoate, Butoxypolypropylene glycol (BPG), Carboxin/Oxycarboxin, Commodity Fumigants (Aluminum Phosphide, Magnesium Phosphide, Phosphine, Propylene Oxide

⁵ XXXXX-XX, Notice, Pesticide Registration Review; Draft Human Health and/or Ecological Risk Assessments for Paraquat; Notice of Availability

(PPO) and Inorganic Sulfites), Cyhalothrins, DBNPA, Halohydantoins, Irgarol, Kaolin, Methoprene, Kinoprene and Hydroprene, Myclobutanil, Naphthalene Acetic Acid (NAA), Organic Esters of Phosphoric Acid (OEPA), *Paecilomyces* species, *Streptomyces lydicus* strain WYEC 108, Triphenyltin hydroxide (TPTH), Triallate, and Triticonazole. ⁶

i. 1,3-Dichloropropene (Telone):

<u>Summary of PID:</u> The PID will include a Fumigant Management Plan (FMP) for all labels (1,3-D does not currently have an FMP) as well as updating respirator language on the labels to the current standard language.

Anticipated Stakeholder Reaction: Minimal press is anticipated, however, on the draft risk assessments OCSPP received a letter from eight state Attorneys General questioning the cancer reclassification and approach for cancer risk assessment. No communications rollout is proposed; OCSPP/OPA will have a desk statement on-hand for any press inquiries.

ii. 1-Methylcyclopropene:

Summary of PID: No mitigation or labeling changes are needed.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

iii. Beauveria bassiana:

Summary of PID: No mitigation or labeling changes are needed.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

iv. Benzyl benzoate:

<u>Summary of PID:</u> No mitigation is proposed.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

v. Butoxypolypropylene glycol (BPG):

Summary of PID: No mitigation is proposed.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

vi. Carboxin/Oxycarboxin:

⁶ XXXXX-XX, Notice, Pesticide Registration Review; Proposed Interim Decisions for Several Pesticides; Notice of Availability

Summary of PID: OCSPP is proposing the addition of a PF10 respirator for the nine identified inhalation scenarios of concern. OCSPP is proposing updated mandatory seed management and planting language to reduce risk of birds and mammals consuming treated seeds left exposed in fields. Proposed label changes include requiring a minimum 4-month plant-back interval for unregistered crops (carboxin labels only) and updated pesticide resistance management language.

<u>Anticipated Stakeholder Reaction:</u> Minimal stakeholder feedback is expected on most proposed mitigations and label changes. No communications rollout is proposed beyond the normal public notice and comment period.

vii. Commodity Fumigants (Aluminum Phosphide, Magnesium Phosphide, Phosphine, Propylene Oxide (PPO) and Inorganic Sulfites (Sulfur Dioxide and Sodium Metabisulfite):

Summary of PID: For aluminum phosphide, magnesium phosphide, phosphine, propylene oxide (PPO) and sulfur dioxide: To protect workers and bystanders, OCSPP is proposing revised fumigation management plans (FMPs). FMPs describe how and when a fumigant will be applied, include plans to respond to leaks or accidents, specify storage guidelines, and outline other protective measures such as active monitoring of fumigant air concentrations. OCSPP is also proposing some buffer zones around treatment sites. A buffer zone is a radius around an application site that personnel may enter only if wearing PPE during application and aeration times. Buffer zones are calculated on site depending on chamber size, application rate, stack height and configuration, and other factors. For sodium metabisulfite: No mitigation is proposed for the antimicrobial uses of sodium metabisulfite. Additionally, mitigation for PPO applies to both conventional and antimicrobial uses.

<u>Anticipated Stakeholder Reaction:</u> No communications rollout is proposed beyond the normal public notice and comment period. OCSPP has been actively communicating with commodity fumigant product registrants throughout the risk assessment and mitigation development process.

viii. Cyhalothrins (gamma-Cyhalothrin & lambda-Cyhalothrin):

<u>Summary of PID:</u> The cyhalothrins are labeled for agricultural uses which pose potential risks to pollinators, and therefore the PID will propose updated environmental hazards, and information on incident reporting, managed pollinator protection plans, and pollinator best management practices. The PID will also propose prohibition of certain application methods and require additional PPE to address risks of concern identified in the residential and occupational assessment.

- o For gamma-Cyhalothrin: For residential handlers, the PID proposes prohibition of use of manually-pressurized hand-wand, hose-end sprayers, backpack sprayers and sprinkler applications. For residential post-application: (1) prohibit indoor coarse spray and pin-stream applications to carpets, and (2) restrict outdoor use to direct ground application. For occupational handlers: (1) prohibit aerial broadcast sprays to typical field crops, (2) prohibit use of different types of handheld equipment for several use sites, (3) prohibit use of flaggers, and (4) require a combination of additional PPE such as gloves, double layer clothing, PF10 respirator, and engineering controls. For occupational post-application: increase REIs for several activities. This chemical is not widely used in agriculture; restrictions/cancellations may have limited effect.
- o For lambda-Cyhalothrin: For residential post-application: (1) prohibit indoor use on mattresses, and (2) restrict turf uses to golf courses only. For occupational handlers: (1) prohibit use of different types of handheld equipment for several use sites such as nurseries, landscape/turf, orchards and vineyards, greenhouses, industrial/commercial settings, and typical field crops, and (2) require a combination of additional PPE such as gloves, double layer clothing, and PF10 respirator. For occupational post-application: increase REIs for some activities.

<u>Anticipated Stakeholder Reaction:</u> No communication rollout is proposed beyond the normal public notice and comment period.

ix. DBNPA:

<u>Summary of PID:</u> The proposed mitigation strategy is to cancel the material preservative uses of DBNPA in paints, coatings, stains, pigment, dye, filler suspensions, polymer dispersions, and emulsions. For material preservative uses in paper mill additives, adhesives, glues, and tackifiers, the proposed mitigation is to implement closed loading and delivery systems. To address aggregate exposure to children, the proposed mitigation is to reduce the application rate of household cleaners to 25 ppm. For occupational exposure to material preservatives in cleaners, the proposed mitigation is to reduce the application rate to 25 ppm.

Anticipated Stakeholder Reaction: Due to respiratory risks, several uses are being proposed for removal. Ongoing and frequent stakeholder communication is anticipated.

x. Halohydantoins:

<u>Summary of PID:</u> To mitigate the inhalation risks identified for occupational handlers, OCSPP is proposing to require that halohydantoin products no longer be formulated as powders and granules. The proposed mitigation is to require that halohydantoin products

be formulated only as pellets, tablets or pucks, which are expected to have negligible inhalation exposures.

<u>Anticipated Stakeholder Reaction:</u> Due to the formulation restrictions being proposed, moderate stakeholder feedback is anticipated. Communication with stakeholders is ongoing.

xi. Irgarol:

Summary of PID:

- Residential inhalation: Preserved algicidal paint (DIY) use via airless sprayer lower the application rate
- Residential dermal:
 - O Anti-foulant Paint (AFP) use: cancel the AFP uses
 - Preserved algicidal paint (DIY) use: Brush and roller lower the application rate
- Occupational handler inhalation:
 - Anti-foulant Paint (APF) use: cancel the AFP uses.
 - O Paint preservative use: Airless sprayer lower application rate; Open-pour respirator or closed loading
- Occupational handler dermal:
 - Materials preservative: Open-pour powder goggles or face shield and rubber gloves and protective clothing
- Ecological concerns: Deletion of AFP use.

<u>Anticipated Stakeholder Reaction:</u> No communications rollout is proposed, and OCSPP will have a desk statement on hand for any press inquiries. All registrants have been informed of the proposed AFP use cancellation and generally agree with cancellation of the AFP use. Stakeholders will also have an additional chance to provide public comments on our PID.

xii. Kaolin:

Summary of PID: No mitigation or labeling changes are needed.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xiii. Methoprene, Kinoprene and Hydroprene:

Summary of PID: No mitigation or labeling changes are needed.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xiv. Myclobutanil:

Summary of PID: Proposed mitigation measures include:

- Cancellation of residential turf use, dust product formulation, and on-farm cotton seed treatment.
- Requiring a 24-hour REI for sod uses, and up to a 2-day REI on turning and girdling table grapes.
- Requiring "chemical-resistant headgear" (instead of currently listed "hat") for airblast applications.
- Requiring double layer of clothing and gloves with all backpack and mechanically pressurized handgun equipment uses.
- Adding advisory spray drift language.

<u>Anticipated Stakeholder Reaction:</u> No communications rollout is proposed beyond the normal public notice and comment period.

xv. Naphthalene Acetic Acid (NAA):

<u>Summary of PID:</u> For human health risk, proposed mitigation includes requiring additional PPE (respirators) for occupational workers. For ecological risk, proposed mitigation includes changes to application rates for pomegranate and mandarin uses (reducing number of total applications per year), requiring mandatory and advisory spray drift language, and non-target advisory statements.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xvi. Organic Esters of Phosphoric Acid (OEPA):

<u>Summary of PID</u>: The PID includes the risk mitigation measures from the RED, such as prohibiting the product from being incorporated into molded polymer products (e.g., toys), reducing the rates for various uses, including carpet and textile use, closed loading systems, and PPE requirements. The mitigation for the paint use is different from the RED in that it proposes to reduce the max rate from 5% to 0.25%. Registrants want the use at a rate of 2%.

Anticipated Stakeholder Reaction: Overall stakeholder reaction is anticipated to be low. OCSPP is proposing to lower the paint use rate below what registrants have indicated as desired, and they may comment on the PID and request OCSPP to redo the risk assessment if they have refinements to offer.

xvii. Paecilomyces species:

<u>Summary of PID:</u> No mitigation or labeling changes are needed. The agency is making a "no effect" determination under ESA.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xviii. Streptomyces lydicus strain WYEC 108:

<u>Summary of PID:</u> No mitigation or labeling changes are needed. The agency is making a "no effect" determination under ESA.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xix. Triphenyltin hydroxide (TPTH):

<u>Summary of PID:</u> The proposed mitigation measures, to which the registrants have agreed, include:

- Deletion of water-soluble packets (WSP) use.
- Prohibition of backpack and mechanically pressurized handgun applications to pecans.
- Standardized type of closed mixing loading system on all labels: Mechanical Transfer System.
- Mandatory spray drift restrictions:
 - o Increase droplet size restriction to medium or coarser.
 - o Boom height: 3 ft from the canopy for ground applications.
- Spray drift buffers to residential and commercial areas (75 ft).
- Update surface water advisory language.
- Change 'seasonal use rates' to 'annual'.

<u>Anticipated Stakeholder Reaction:</u> No communications rollout is proposed; OCSPP will have a desk statement on-hand for any press inquiries.

xx. Triallate:

<u>Summary of PID:</u> Proposed mitigation includes updated non-target advisory statements, updated spray drift language, and mandatory soil incorporation (already recommended on labels).

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xxi. Triticonazole:

<u>Summary of PID:</u> Proposed mitigation focuses on standardizing advisory label language, including: handling of treated seed; advisory spray drift management; and fungicide resistance management.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

IV. Interim Decisions

The Interim Decisions (IDs) are the fourth step in the four-step process. The ID is followed by OCSPP conducting ESA consultation, which takes some time, so in effect the ID is also the final step for the near term. In the ID, OCSPP requires mitigation measures to reduce the human health and ecological risks identified in step two, considering public comment on the PIDs – step three. No proactive communications are planned for these procedural announcements. OCSPP will have subject matter experts assist with press inquiries should they come in.

A. Interim Decisions for 18 Pesticides

OCSPP will announce the availability of interim registration review decisions for the following 18 pesticides: Boscalid, Chlorine Gas, Cyproconazole, Ethoxyquin, Etoxazole, Fluazifop-P-butyl, Gonadotropin Releasing Hormone (GnRH), MCPA, Mecoprop-p, Methyl bromide, Phenol and Salt, Pinoxaden, Pymetrozine, Pyraclostrobin, Pyraflufenethyl, Pyrethroids (Bifenthrin, Cyfluthrins, Cyphenothrin, Deltamethrin, Esfenvalerate, Fenpropathrin, Imiprothrin, Permethrin, Phenothrin, Prallethrin, Tau-fluvalinate, Tefluthrin, and Tetramethrin), Terbuthylazine, and Thiabendazole (dual use).

i. Boscalid:

<u>Summary of ID:</u> To mitigate risks of concern, OCSPP is requiring mandatory spray drift management language, the use of gloves for certain handler scenarios, an increased REI for certain post-application activities in grapes, directions for the user to clean up spilled treated seed, and updates to surface and ground water advisories.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

ii. Chlorine Gas:

<u>Summary of ID:</u> Required mitigation includes designation of chlorine gas as a RUP for all uses except potable water and wastewater treatment, label changes to incorporate key label elements from supplemental labeling onto the actual pesticide labels (such as application rate, application method, use sites, specific directions for use, PPE, storage and disposal instructions, first aid and precautionary statements), and allowing citations to third-party pamphlets for additional guidance, and adding label language for discharging chlorine-treated pool water.

⁷ XXXXX-XX, Notice, Pesticide Registration Review; Interim Decisions and Case Closures for Several Pesticides; Notice of Availability

<u>Anticipated Stakeholder Reaction:</u> Positive feedback from numerous stakeholders, including registrants, was received on the PID, and minimal stakeholder feedback is anticipated.

iii. Cyproconazole:

<u>Summary of ID:</u> Required mitigation includes reducing potential ecological risks by including advisory spray drift language and fungicide resistance management.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

iv. Ethoxyquin:

<u>Summary of ID:</u> Given the chemical's limited use pattern (indoors only) and environmental fate, the agency determined *de minimis* ecological risk, and issued a "no effects" determination.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

v. Etoxazole:

<u>Summary of ID:</u> To mitigate the potential concerns for occupational handlers, OCSPP is requiring respiratory protection for some uses and formulations. To address potential risks of concern to pollinators and aquatic invertebrates, the agency is requiring that product labels include updated spray drift management language.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

vi. Fluazifop-P-butyl:

<u>Summary of ID:</u> To mitigate the mixer/loader risks, the agency will increase the PPE requirements for mixing/loading liquids for aerial applications. To mitigate the mixer/loader/applicator risks, the agency will require dilution of the spray solution by requiring a minimum spray volume of 55 gallons per acre for mechanically pressurized handgun applications. To mitigate the potential ecological risks, the agency will require enforceable spray drift language on all labels.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

vii. Gonadotropin Releasing Hormone (GnRH):

<u>Summary of ID</u>: OCSPP made a "no effect" determination under the ESA for all listed species and did not propose or require any further data or mitigation measures. An exemption order for EDSP has been signed.

Anticipated Stakeholder Reaction: There was no stakeholder reaction to the combined GnRH Final Work Plan (FWP)/ DRA/PID, and as a result, the agency anticipates minimal reaction to the ID.

viii. MCPA:

<u>Summary of ID:</u> During the comment period on the PID, the MCPA Task Force Three (MCPA TF3) identified errors in the revised draft risk assessment, resulting in an additional version of the revised draft risk assessment. Updated mitigation required in the ID includes the prohibition of backpack sprayers for rights-of-way, additional PPE, a 24-hour REI, mandatory and advisory spray drift requirements, updated environmental hazards statements, resistance management, and various label cleanup measures. OCSPP has met with the MCPA TF3, and the registrants have agreed to the mitigation.

The IR-4 Project commented on the PID regarding the preliminary data from the field trials, indicating that residues will be below the existing tolerances for clover forage and clover hay. The IR-4 project anticipates submitting data to OCSPP to amend an established tolerance. At this time, the data have not yet been submitted.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

ix. Mecoprop-p:

<u>Summary of ID:</u> Required mitigation focuses on reducing ecological risks by issuing mandatory and advisory spray drift management, language to not apply when weeds are flowering, herbicide resistance management, and ensuring the REI is consistent on all labels at 48-hours.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

x. Methyl bromide:

<u>Summary of ID:</u> The PID outlined labeling updates, including amendments to PPE language, clarification of directions for use in shadehouses, strengthening existing fumigant management plan (FMP) requirements for commodity applications, and removing expired Critical Use Exemptions (CUE) uses from all existing labels. Based on stakeholder comments, the ID retains the CUE uses on labels and clarifies CUE label statements.

<u>Anticipated Stakeholder Reaction:</u> The Methyl Bromide Industry Panel, USDA and growers who commented disagreed with the removal of all CUE uses from labels. Comments submitted on the PID expressed overall concerns over the removal of these

uses from labels, despite these exemptions no longer being in effect. These stakeholders should be satisfied that these CUE uses will not be removed.

xi. Phenol and Salt

<u>Summary of ID</u>: The following mitigation was proposed in the PID: (1) remove food-contact surface uses, (2) require occupational handlers to wear chemical resistant gloves, and (3) require PF10 respirators for remediation workers and/or limit the frequency and time of use to one hour per day. No changes were made to this mitigation strategy since the PID.

<u>Anticipated Stakeholder Reaction:</u> Minimal stakeholder reaction is anticipated. Stakeholders were consulted when making the mitigation strategy and no comments were received on the PID.

xii. Pinoxaden:

<u>Summary of ID:</u> Required mitigation to reduce ecological risk includes mandatory spray drift language, a non-target organism advisory statement, herbicide resistance management language, and a requirement that all products labeled for use on wheat and barley specify the maximum annual application rate.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xiii. Pymetrozine:

<u>Summary of ID:</u> Required mitigation includes restrictions on use on vulnerable soils and well setback and/or runoff management system for an outdoor ornamental/nursery production scenario, rate reductions for ornamentals grown outdoors, respirators for mixers and loaders of aerial and chemigation application equipment, advisory spray drift reduction language, insecticide resistance management, and updating maximum applications per year.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.

xiv. Pyraclostrobin:

<u>Summary of ID:</u> The mitigation in the PID included: (1) PPE for occupational handlers-in-field uses, (2) engineering control requirement, (3) modifing REIs, (4) spray drift management language, (5) environmental hazard statements, and (6) fungicide resistance management language. Comments on the PID opposed the long REIs in grapes. USDA and grower groups questioned the way OCSPP described and assessed certain activities, which seems to be a common issue across multiple fungicides and insecticides used in grapes. Since the PID, the proposed 8-18 day REI for grape turning and girdling has

been revised to a 12 hour REI based on dislodgeable foliar residue (DFR) data. The proposed 5-8 day REI for grape leaf tying/training and leaf pulling has been revised to a 5-day prohibition for these activities based on the benefits of pyraclostrobin. Additionally, based on the results of the Tier I and available Tier II pollinator data, OCSPP is requesting submission of higher Tier pollinator studies.

<u>Anticipated Stakeholder Reaction:</u> Stakeholder reaction to the PID was minimal, and based on the changes to the proposed mitigation it is anticipated that there will be minimal reaction to the ID.

xv. Pyraflufen-ethyl:

<u>Summary of ID:</u> The following mitigation was proposed in the PID: (1) update gloves statement, (2) mandatory and advisory spray drift language, (3) herbicide resistance management language, and (4) non-target organism advisory. No changes have been made since the PID.

<u>Anticipated Stakeholder Reaction:</u> Stakeholder reaction to the PID was minimal, and it is anticipated that there will be minimal reaction to the ID.

xvi. Pyrethroids (Bifenthrin, Cyfluthrins, Cyphenothrin, Deltamethrin, Esfenvalerate, Fenpropathrin, Imiprothrin, Permethrin, Phenothrin, Prallethrin, Tau-fluvalinate, Tefluthrin, and Tetramethrin):

Summary of ID: Ten pyrethroids pose no human health risks of concern. Three IDs finalize mitigation proposed in the PIDs to reduce potential residential post application and occupational handler risks. Bifenthrin use requires mitigation to address potential residential post application risk. Bifenthrin, cyfluthrins, and prallethrin uses require mitigation to address potential occupational handler risks. Ecological mitigation focused on addressing runoff and spray drift concerns. Nine pyrethroids are labeled for agricultural uses which pose potential risks to pollinators (except tefluthrin), and, therefore, the IDs finalize pollinator labeling as proposed in the PIDs. Pollinator labeling includes updated environmental hazards, and information on incident reporting, managed pollinator protection plans, and pollinator best management practices. Additional tier I pollinator data will be required for cases without a complete dataset.

Anticipated Stakeholder Reaction and Communications: Comments on the PIDs and the Ecological Risk Mitigation Proposal were received from registrants, state and regional agencies, university extensions, non-governmental organizations, crop and trade organizations, the USDA, grower groups, and Pest Control Operators (PCOs). These comments did not result in changes to the human health aspects of the PIDs. Comments on the ecological risk mitigation resulted in minor adjustments to the proposed runoff

and/or spray drift labeling. The pyrethroid registrants requested that OCSPP update the quantitative risk numbers in the ecological risk assessment based on information provided to OCSPP. While OCSPP is not updating the quantitative risk numbers, OCSPP had previously considered the information, and data provided by various sources qualitatively in the risk assessment was extensively cited and relied on in OCSPP's risk management decision. An OPP update, press release, and web updates are proposed for the release of the pyrethroids IDs.

xvii. Terbuthylazine

<u>Summary of ID:</u> No human health risks were identified. However, terbuthylazine is toxic to aquatic organisms (including plants). Therefore, label changes are being required to reduce ecological exposures from discharges by recirculating cooling towers and when draining ornamental/decorative fountains.

Anticipated Stakeholder Reaction: Minimal stakeholder reaction is anticipated.

xviii. Thiabendazole (dual use):

<u>Summary of ID:</u> Occupational risks of concern from conventional uses resolve with the addition of a respirator. Occupational risks of concern from antimicrobial uses resolve with a reduction in the use rate. Data on thiabendazole content of spent mushroom compost has been provided to the agency and conversations are ongoing with the registrants and the American Mushroom Institute on how to utilize this data in the future.

Anticipated Stakeholder Reaction: Minimal stakeholder feedback is anticipated.